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| APPLICATION NO.   | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.            | CONFIRMATION NO. |
|---|-------------|----------------------|--------------------------------|------------------|
| 10/758,155  | 01/12/2004  | James McSwiggen      | MBHB02-742-N<br>(400/141)      | 5758             |
| 20306 7590 12/18/2006<br>MCDONNELL BOEHNEN HULBERT & BERGHOFF LLP<br>300 S. WACKER DRIVE<br>32ND FLOOR<br>CHICAGO, IL 60606 |             |                      | EXAMINER<br>BOWMAN, AMY HUDSON |                  |
|   |             |                      | ART UNIT                       | PAPER NUMBER     |
|   |             |                      | 1635                           |                  |

| SHORTENED STATUTORY PERIOD OF RESPONSE | MAIL DATE  | DELIVERY MODE |
|--|------------|---------------|
| 3 MONTHS                               | 12/18/2006 | PAPER         |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

# Office Action Summary

Application No.

10/758,155

Applicant(s)

MCSWIGGEN ET AL.

Examiner

Amy H. Bowman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 22 June 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1,3,14-23,32 and 35 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,3,14-23,32 and 35 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 8/7/06, 11/02/06.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Status of Application/Amendment/Claims***

Applicant's response filed 6/22/2006 has been considered. Rejections and/or objections not reiterated from the previous office action mailed 2/22/2006 are hereby withdrawn. The following rejections and/or objections are either newly applied or are reiterated and are the only rejections and/or objections presently applied to the instant application.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1, 3, 14-23, 32 and 35 are pending in the instant application.

### ***Response to Priority***

In applicant's remarks filed on 6/22/2006, applicant discloses that newly introduced SEQ ID NO: 2752 refers to GenBank accession No. NM\_002019 for VEGFr1 RNA. However, the instant claims recite that SEQ ID NO: 2752 is both VEGFr1 and VEGFr2. Support for this amendment has not been located in any of the priority documents, nor the instant specification, as explained in the 35 U.S.C. 112, first paragraph, rejection below. Therefore, the effective filing date of the instant claims is determined to be that of the instant application, 10/758,155, which has an effective filing date of 1/12/2004.

The instant claims do not receive the benefit of any of the earlier filed priority documents because each of the documents do not teach an identical sequence for

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VEGFr1 and VEGFr2 (instantly recited SEQ ID NO: 2752) and do not teach a limitation wherein each strand is independently about 14 to 28 nucleotides in length, the antisense strand comprises about 14 to 28 nucleotides that are complementary to VEGFr1 and VEGFr2 of an identical sequence, and the sense strand comprises a portion of the VEGFr1 and VEGFr2 sequence of about 18 to about 27 nucleotides.

Thus, in view of the instant claim amendments, the instant claims are accorded an effective filing date of 1/12/2004. Should applicants disagree, applicants are encouraged to point out with particularity by page and line number where such support might exist in each intervening document. In order to properly claim priority, it is noted that support for each of the claim limitations must exist in each of the intervening documents.

### ***Response to Double Patenting***

Claims 1, 3, 14-23, 32 and 35 stand provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-30 of copending Application No. 10/664,668 and claims 49-51 and 58-76 of copending Application No. 10/444,853.

Applicant has requested consideration of filing a terminal disclaimer upon allowance of the pending claims.

***New Objections/Rejections***

***Sequence Compliance***

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 because the CRF is flawed technically and could not be entered into the database. Therefore, SEQ ID NO: 2752, as instantly recited, could not be searched or examined. Please see that attached "Raw Sequence Listing Error Report" for details.

A complete response to this office action must correct the defects cited above regarding compliance with the sequence rules and a response to the action on the merits which follows.

The aforementioned instance of failure to comply is not intended as an exhaustive list of all such potential failures to comply in the instant application. Applicants are encouraged to thoroughly review the application to ensure that the entire application is in full compliance with all sequence rules. This requirement will not be held in abeyance.

***Claim Objections***

Claim 3 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is

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required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

Claim 3 is drawn to the siRNA molecule of claim 1, wherein said siRNA molecule comprises ribonucleotides. However, the siRNA molecule of claim 1 necessarily comprises ribonucleotides, hence the title "siRNA". Therefore, claim 3 fails to further limit claim 1.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 3, 14-23, 32 and 35 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Instant claim 1 recites VEGFr1 and VEGFr2 as each corresponding to instant SEQ ID NO: 2752. The CRF filed by applicant is flawed and therefore could not be entered into the database. Therefore, SEQ ID NO: 2752 could not be searched or examined. Upon a review of the art, VEGFr1 and VEGFr2 do not have an identical sequence. Therefore, it is unclear what applicant intends to claim because the claims recite two different targets by title, VEGFr1 and VEGFr2, but recite a single SEQ ID NO. Therefore, the claims could not be further treated on the merits.

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The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 3, 14-23, 32 and 35 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. **This is a new matter rejection.**

Claims 1, 3, 14-23, 32 and 35 are directed to a chemically modified double stranded siRNA molecule wherein each strand is independently "about 14 to 28 nucleotides in length" and the antisense strand comprises "about 14 to 28 nucleotides that are complementary" to SEQ ID NO: 2752 or a portion thereof.

The specification does not contemplate a limitation wherein the length of each of the strands of the siRNA is "about 14 to 28 nucleotides in length" and the antisense strand comprises "about 14 to 28 nucleotides that are complementary" to SEQ ID NO: 2752 or a portion thereof and hence does not provide support for such.

Furthermore, the instant specification does not teach both VEGFr1 and VEGFr2 corresponding to the same SEQ ID NO, SEQ ID NO: 2752, as instantly recited.

Therefore, these claim limitations that were newly introduced in the claim amendments filed 6/22/2006 constitute new matter.

Applicant's arguments filed 6/22/2006 point to page 21 of the instant specification for such support. A review of the specification, and particularly page 21, does not reveal support for where each of these claim amendments are found. Should applicant disagree, applicants are encouraged to point out with particularity by page and line number where such support might exist for each claim limitation added in the amended claims filed on 6/22/2006.

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.



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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy H. Bowman whose telephone number is (571) 272-0755.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Doug Schultz can be reached on (571) 272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

AHB

  
JAMES SCHULTZ, PH.D.  
PRIMARY EXAMINER